REMARKS

Amendments

Claims 1-6, 9-10, 15-17, 19, and 22 have been amended to place the claims in accordance with U.S. patent practice. Claims 5, 6, and 10 have been amended to remove the dependency of a multiple dependent claim upon another multiple dependent claim. Claim 17 was amended to remove an improper dependency upon claim 10. Claim 22 was amended to correct a typographical error in the dependencies of the claim Claims 11-14, 20-21, and 23 have been canceled.

New claim 24 is directed to an embodiment of the invention deleted form original claim 2. New claim 25 is supported by claims 11 and 12, now canceled. New claim 26 is supported by claims 15 and 16. New claim 27 is supported by claim 23, now canceled.

Applicants submit that no new matter is introduced by any of the amendment to the claims.

Claims 1-2, 4-5, 9-10, 15-19, and 22-Version With Markings to Show Changes Made:

1. An oral pharmaceutical formulation comprising therapeutically effective amounts of an inhibitor compound of the ileal bile acid transport system of a patient (IBAT inhibitor compound) and a pharmaceutically acceptable carrier, wherein the formulation is formulated [designed] to deliver the IBAT inhibitor compound to [in] the ileum of the patient.

2. The oral pharmaceutical formulation according to claim 1, wherein the formulation is formulated [designed] to deliver the IBAT inhibitor compound to [in] the ileum by release in [one or more parts of the body selected from the] the distal jejunum or [and] the proximal ileum [, and/or directly in the ileum].

3. The formulation according to claim 1, wherein the carrier is formulated [designed] to deliver the IBAT inhibitor compound to [in] the ileum.

4. The formulation according to claim 1, wherein the carrier is formulated [designed] to release the IBAT inhibitor compound in the distal jejunum or [and] in the proximal ileum.

5. The formulation according to claim 1 [any one of claims 1 to 4], wherein the carrier is formulated [designed] to give a minimum release of the IBAT inhibitor compound in the upper part of the small intestine.

6. The formulation according to claim 1 [any one of claims 1 to 4], wherein the pharmaceutical formulation is a delayed release formulation.

9. The formulation according to claim 6, wherein release of the IBAT inhibitor compound from the delayed release formulation is triggered by a [the] pH difference[s] between the jejunum and ileum.

10. The formulation according to claim 1 [any one of claims 1 to 9], wherein the IBAT inhibitor compound is a low permeability drug as defined in the FDA Biopharmaceutical Classification System [FDA].

15. A method for the prophylactic or therapeutic treatment of a subject suffering from, or susceptible to, hypercholesterolemia, comprising [which method comprises] administering to the subject a therapeutically effective amount of the pharmaceutical formulation as claimed in [designed according to] any one of claims 1 to 10.

16. A pharmaceutical formulation for simultaneous, separate or sequential administration for [in] the prophylactic or therapeutic treatment of hypercholesterolemia, comprising therapeutically effective amounts of [which formulation comprises] an inhibitor compound of the ileal bile acid transport system of a patient (IBAT inhibitor compound) and a bile acid binder.

17. The pharmaceutical formulation according to claim 16, wherein the IBAT inhibitor compound is a low permeability drug as defined in the FDA Biopharmaceutical Classification System [claim 10].

19. The pharmaceutical formulation according to claim 18, formulated to release [wherein] the bile acid binder in the colon [is in a formulation with colon release].

22. A method for the prophylactic or therapeutic treatment of a subject suffering from, or susceptible to, diarrhea [diarrhoea] during therapy comprising administration of an IBAT inhibitor compound, comprising [which method comprises] administering to the subject a therapeutically effective amount of the [a] pharmaceutical formulation [designed] according to any one of claims 16 to 19 [15 to 18].

CONCLUSION

Upon entry of this Preliminary Amendment, claims 1-10, 15-19, 22, and 24-27 are pending. Applicants respectfully submit the claims 1-10, 15-19, 22, and 24-27 are directed to patentable subject matter. Accordingly, Applicants request allowance of the claims.

Authorization is hereby given to charge any fee in connection with this communication with this communication to Deposit Account No. 23-1703.

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Respectfully submitted,

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